

Notice of Allowability

Application No.

10/048,123

Examiner

Binta M. Robinson

Applicant(s)

BLACKLER ET AL.

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 3/29/04 and 4/30/04.
2. ☒ The allowed claim(s) is/are 15, 16, 17, 18, 19, 20, 21, 25, 26, 27, 28, 29, 30-35, 42 respectively (renumbered as claims 1-19, respectively).
3. ☒ The drawings filed on 10/22/01 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Johann Richter
JOHANN RICHTER
SUPERVISORY PATENT EXAMINER
GROUP 1220

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

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Claims 15, 16, 17, 18, 19, 20, 21, 22, 25, 26, 27, 28, 29, 30-35, 42 are now pending.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

1) After the title, in the first line of the specification filed 10/22/01, insert the phrase "This application is a 371 of PCT/GB00/01520 filed 04/19/2000".

Authorization for this examiner's amendment was given in a telephone interview with Kathy Sieburth on 5/26/04.

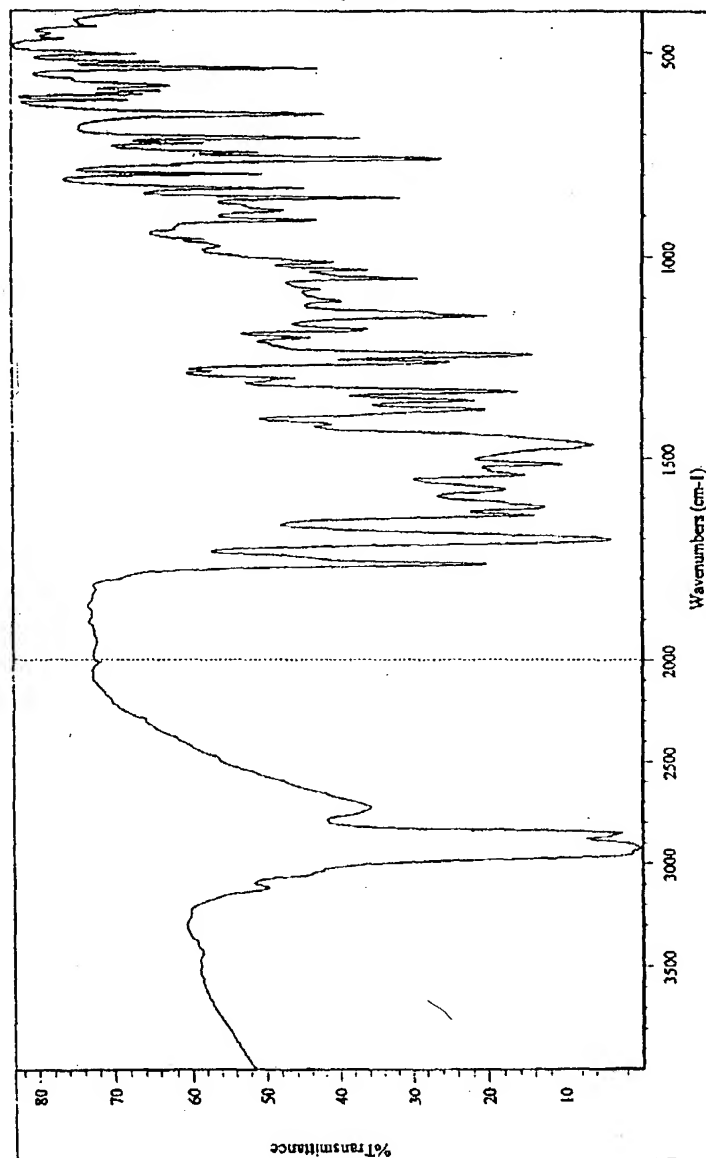
The application has been amended as follows:

A. In claim 28, lines 1-2, page 9 of the claim amendment filed 3/29/04, the phrase "A method for the treatment or prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof" is amended to -----
A method for the treatment of diabetes mellitus--.

B. Claim 22 on page 9, lines 1-2 of the amendment filed 3/29/04, is cancelled.

C. On page 3, of the amendment filed 3/29/04, in claim 16, the phrase "A compound which is a polymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt, wherein said compound, in a mineral oil dispersion, provides an infra red spectrum substantially in accordance with Figure I:

Figure I



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Is amended to -----A compound which is a polymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt, wherein said compound, in a mineral oil dispersion, provides an infrared spectrum substantially in accordance with Figure I----

D. On page 4, of the amendment filed 3/29/04, in claim 17, the phrase "A compound which is a polymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt, wherein said compound provides a Raman spectrum substantially in accordance with Figure II:

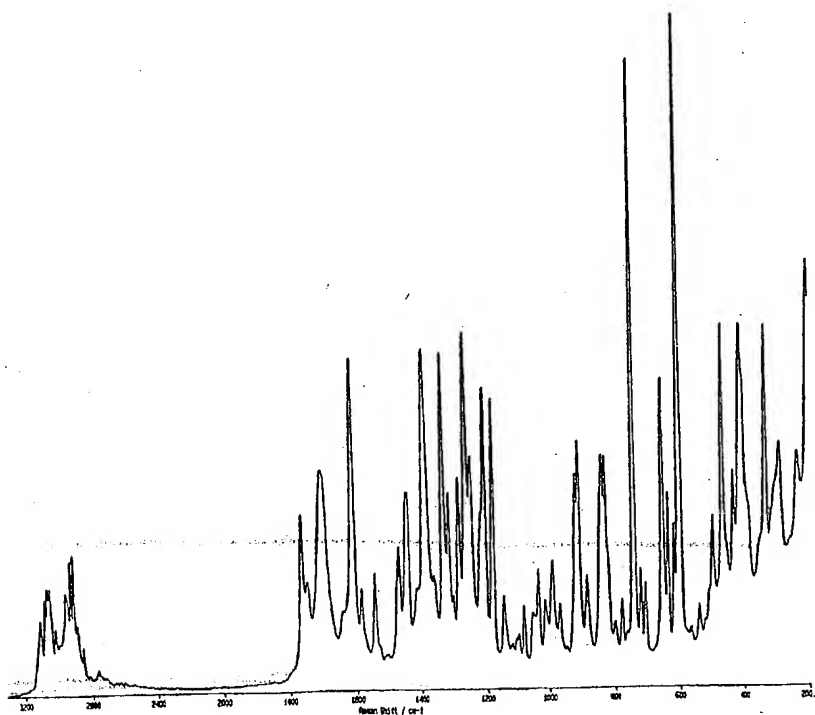
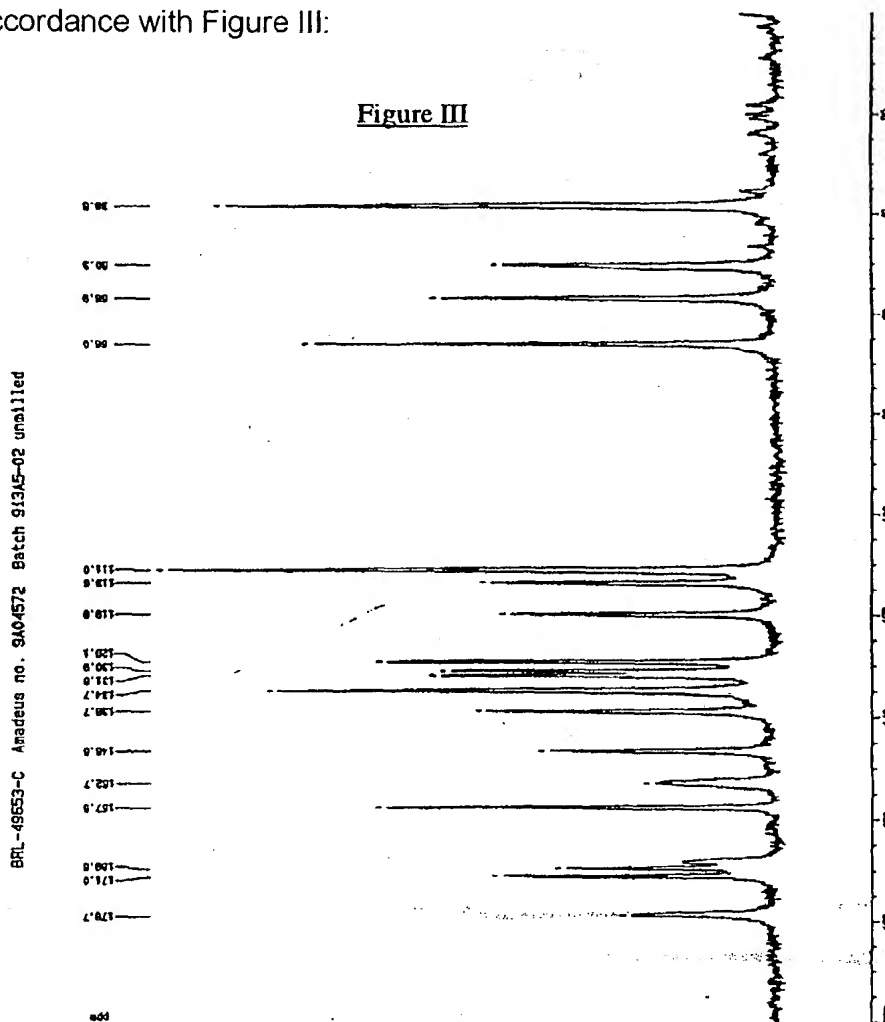


Figure II

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Is amended to -----A compound which is a polymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt, wherein said compound provides a Raman spectrum substantially in accordance with Figure II.-----

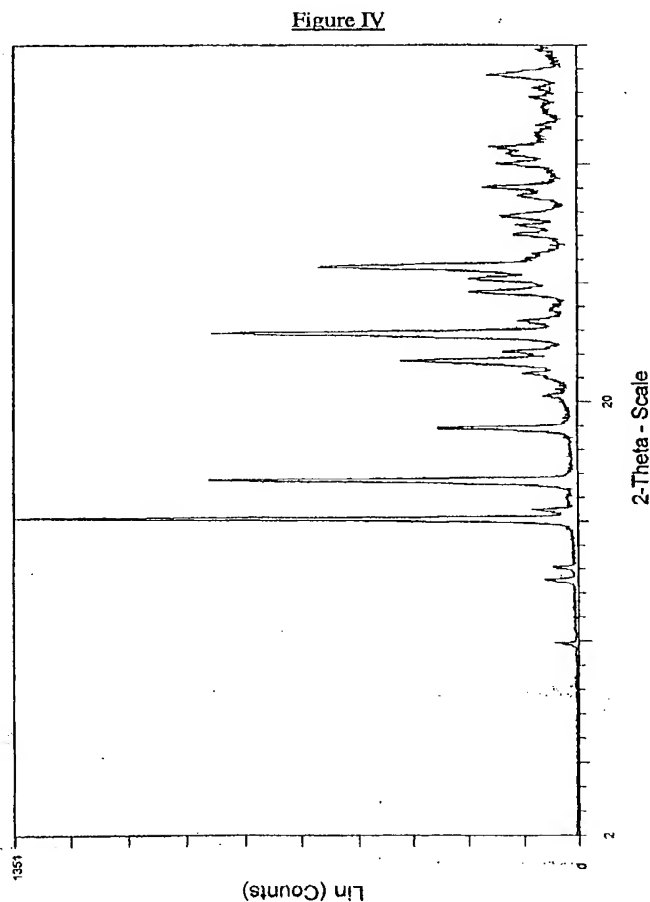
E. On page 5, of the amendment filed 3/29/4, in claim 18, the phrase "A compound which is a polymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt, wherein said compound provides a solid-state ^{13}C nuclear magnetic resonance spectrum substantially in accordance with Figure III:



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Is amended to ----- A compound which is a polymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt, wherein said compound provides a solid-state ^{13}C nuclear magnetic resonance spectrum substantially in accordance with Figure III.-----

F. On page 7 of the amendment filed 3/29/04, in claim 20, the phrase "A compound which is a polymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt, wherein said compound provides an X-ray powder diffraction pattern substantially in accordance with Figure IV:



Is amended to --- A compound which is a polymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt, wherein said compound provides an X-ray powder diffraction pattern substantially in accordance with Figure IV.-----

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

The closest prior art reference is Giles et. al. (See Reference N). The difference between the Giles compound and the instantly claimed compound is the claiming a polymorphic form versus a nonpolymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione. In the instant claims, the maleic salt of the polymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione is a claimed with X-ray diffraction patterns. In the Giles prior art, the nonpolymorphic form o 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione is claimed. At page 12, line 14-16, see the Giles compound

The prior art reference does not teach nor suggest to one of ordinary skill in the art how to modify the prior art compound to derive the instant compound. Accordingly, the instant claims are allowable therefrom.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 886-217-9197 (toll-free).



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Supervisory Patent Examiner